MONTANA CANCER CONTROL PROGRAMS
MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

POLICY AND PROCEDURE FOR ACCESS TO IDENTIFIED PATIENT DATA WITH INFORMED CONSENT FOR RESEARCH FROM THE MONTANA CENTRAL TUMOR REGISTRY

The Montana Central Tumor Registry of the Department of Public Health and Human Services collects data based on the reporting of cancer cases under Montana statutes MCA-2007-50-15-703 and 50-15-705. These data are confidential and access to them is strictly regulated by Montana statutes MCA-2007-50-15-704 and 50-16-603. Release of any data contained in the Montana Central Tumor Registry is subject to additional restrictions regarding medical information imposed by the Health Insurance Portability and Accountability Act (HIPAA) and all other applicable federal laws.

This policy establishes guidelines and procedures to allow constructive research, analysis, and use of the data while protecting the integrity and confidentiality of the Montana Central Tumor Registry in compliance with state statutes and federal laws. To do this, the Montana Central Tumor Registry will consider requests to enter into Data Use Agreements which protect the privacy of the information provided to institutions or investigators.

The Montana Central Tumor Registry may, at its discretion, provide individually identified cancer data to institutions or investigators conducting public health or epidemiologic research, provided all individuals affected have provided explicit, written informed consent.

Under no circumstances shall any information be given to any organization or individual in order to solicit sale of a product, offer any service for compensation, distribute partisan literature, or use for any other political or commercial purpose.

Definition of Informed Consent:

The Montana Code Annotated - 2007 specifies that

> **50-16-603 Confidentiality of health care information.** Health care information in the possession of the department, a local board, a local health officer, or the entity's authorized representatives may not be released except: …..(2) when the health care information pertains to a person who has given written consent to the release and has specified the type of information to be released and the person or entity to whom it may be released;...

There is no provision in Montana statute for the waiver of informed consent for the release of individually identifiable data under any circumstances.

Informed consent must

- be provided individually by each participant for whom data are requested, and
- be in writing, and
- specify the investigator or institution to whom the data are to be released, and
- specify the data elements to be released, and
- be signed and witnessed according to Institutional Review Board (IRB; see page 4) specifications.

By Montana statute, informed consent cannot be waived for deceased individuals. Informed consent for deceased individuals may be provided by the legally designated next-of-kin or other recognized legal representative, provided this is addressed explicitly in the IRB approval. The legal standing of the legal representative must be documented.

The Montana Central Tumor Registry's Data Use Review Committee will determine the extent to which specific data elements requested are adequately covered by the informed consent. The Committee reserves the option to refer the request to the Montana Department of Public Health and Human Services' Legal Counsel for advice.

Case Matching and Identification of Valid Matches

In order to adequately protect the privacy of all patients, the Montana Central Tumor Registry will only release data for individuals who have a very high probability of being valid matches with the study participants who have provided informed consent. The Montana Central Tumor Registry requires, at a minimum, the following data elements to be included in the matching process:

- Full name (first name, middle name preferred/middle initial accepted, last name, and maiden name if applicable)
- Date of birth
- Social security number

A valid match is one who is

- fully matched using a deterministic algorithm; or
- has a 95% or greater probability of being a valid match using a probabilistic algorithm, confirmed by manual review; or
- has a lower than 95% probability using a probabilistic algorithm but who is determined to be a valid match through manual review using additional data elements.

Manual review of probabilistic matches will be conducted independently by two members of the Montana Central Tumor Registry staff and will be documented for the Data Use Review Committee.

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The Montana Central Tumor Registry's Data Use Review Committee:

The Data Use Review Committee is made up of the Manager of the Cancer Surveillance and Epidemiology Program, the Data Use Officer of the Montana Central Tumor Registry, the State Medical Officer, and a member external to DPHHS. The external member will be selected by the other committee members on the basis of knowledge of research design and familiarity with human subjects research. The external member will ordinarily serve for 12 months at a time and may be invited to continue serving for an unlimited number of terms.

The Committee will review each request, make a recommendation for approval or disapproval, and forward the request to the Chief of the Chronic Disease Prevention and Health Promotion Bureau for review, and then to the Administrator of the Public Health and Safety Division for final disposition. The Committee, Bureau Chief, or Division Administrator may refer the request to the Legal Counsel of the Department of Public Health and Human Services for advice.

Restrictions of Data Use:

Data sets released by the Montana Central Tumor Registry may be used only for the purposes for which initial approval is granted. No additional use may be undertaken.

Procedure to Request an Identified Data Set:

An institution or investigator must submit a copy of the research protocol and a Montana Central Tumor Registry Data Use Request. The applicant may fax the protocol and signed request, or may send a scanned, signed copy by e-mail.

The Montana Central Tumor Registry's Data Use Review Committee will review the request. If the information provided is not sufficient to evaluate the request, the Review Committee will request clarification from the applicant.

The Data Use Review Committee is charged with balancing the need to protect individual privacy with the desire to have data from the Montana Central Tumor Registry used to further public health and epidemiologic research, To this end, applicant(s) for a data set are asked to provide a description of the research protocol and anticipated analysis, to enable the Committee to make an informed decision.

A written explanation will be provided for provisional or final disapproval of a request. If disapproval is provisional, a revised Data Use Request with resolution of the reasons for provisional disapproval will be considered. If disapproval is final, a revised submission will not be considered.

The applicant of an approved request will be required to pay a $50.00 fee for the preparation of a Data Use Agreement. The Agreement must be signed by the Principal

Investigator and a senior official at the investigator's institution such as the Dean of Research or Vice President for Research Affairs, if applicable, and returned to the Montana Central Tumor Registry, where it will be signed by the Division Administrator and the Chair of the Data Use Review Committee. A signed copy will be returned to the applicant when the data set is released.

Institutional Review Board / Human Subjects Protection Committee Approval:

All applicants requesting a data set for research purposes[§] must have a final IRB or Human Subjects Protection Committee approval from an entity recognized by the Office for Human Research Protections of the US Department of Health and Human Services. All uses of Montana Central Tumor Registry data constitute research with human subjects. No use of Montana Central Tumor Registry data is eligible for exemption from IRB, regardless of the exemption status of the project as a whole. The Montana Central Tumor Registry's Data Use Review Committee will consider, but does not commit to accept, a request that has passed an expedited IRB review and approval process.

Although an applicant's IRB may approve waiver of informed consent under federal guidelines, there is no provision under Montana statute for the waiver of informed consent for the release of individually identifiable data under any circumstances. Montana statute takes precedence over federal guidelines and IRB approval.

In view of the time required for the IRB process, a request may be submitted to the Montana Central Tumor Registry's Data Use Review Committee before IRB approval is final, but the process should be well underway. Provisional approval for a Data Use Agreement may be granted before the IRB process is complete but a data set will not be released until final IRB approval is documented.

Duration of a Data Use Agreement:

A Data Use Agreement will ordinarily be for one year (with potential for renewal), but may not exceed the effective dates of the corresponding IRB approval. If necessary, the applicant must obtain an IRB extension before a Data Use Agreement will be renewed.

It will be the responsibility of the applicant to be sure that IRB extensions and requests for renewal of Data Use Agreements are current. Lapse of either or both will result in the cancellation of a Data Use Agreement.

[§] The Office for Human Research Protection's definition of research is "a systematic investigation designed to develop or contribute to generalizable knowledge."

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Graduate Student Projects:

Graduate students and their academic advisors are encouraged to contact the Manager of the Cancer Surveillance and Epidemiology Program to discuss the possibility of using Montana Central Tumor Registry data sets for professional papers, theses, or dissertations. A formal Data Use Request should not be submitted unless it is agreed that the proposed graduate student project is appropriate and feasible.

A graduate student must complete the standard Data Use Request plus a supplemental section documenting approval of the paper, thesis, or dissertation topic and research plan by a graduate committee or preceptor. The chair of the graduate committee or preceptor must co-sign the request and Data Use Agreement, if granted, with the student.

Because of the need for IRB approvals, Data Use Review Committee action, and the time required for Montana Central Tumor Registry staff to prepare data sets, requests for data sets for other student activities (e.g., term papers, class projects, and most undergraduate uses) will not be considered. Data sets will not be released for instructional purposes.

Multiple Research Projects:

Institutions or investigators using data from the Montana Central Tumor Registry may use it only for the project for which approval was granted. The data provided for one project may not be used for a second or follow-up project without additional written agreements.

Data Use Agreement:

All Data Use Agreements with the Montana Central Tumor Registry are subject to unilateral cancellation at any time at the discretion of the Montana Central Tumor Registry, the Data Use Review Committee, or the Montana Department of Public Health and Human Services.

Each Montana Central Tumor Registry Data Use Agreement will be individually drafted to cover all reasonably anticipated circumstances for each release of the data. **There will be a $50.00 fee for each Data Use Agreement.**

All investigators (excluding direct subordinates of the primary investigator) and all institutions who need access to the data must sign a Data Use Agreement. **Contractual arrangements or other agreements among investigators or institutions may not be used to share Montana Central Tumor Registry data with third parties.**

Each Data Use Agreement will contain, at the minimum, the following elements.

1. Identification of Institution
2. Identification of Primary Investigator

3. Identification of staff supervised by Primary Investigator who will have access to the data in the course of their routine duties.
4. Commitment not to release the data to third parties.
5. Specification of minimum cell size to be suppressed in any reports based on the data set.
6. Agreement to destroy the data set at the end of the project.
7. Commitment to use the data only for the approved project.
8. The effective dates of the Agreement. In general this will be one year, subject to application for renewal.
9. Description of physical and electronic security measures to be use to protect the data.
10. A summary statement listing all uses of the data and a complete copy of the protocol as an Appendix.
11. Description of the method to be used to document informed consent from living participants.
12. Description of the method to be used to document informed consent from next-of-kin of deceased participants, including description of method to be used to document legal standing of next-of-kin to provide consent.
13. Description of the variables to be used to perform matching between the Applicant's participants and cases contained in the Montana Central Tumor Registry.
14. Description of the matching methodology to be employed, including software, matching algorithm, and lower matching threshold.
15. Statement addressing penalties for violation of the Data Use Agreement. At the minimum, violation will result in immediate cancellation of the Data Use Agreement. The Montana Department of Public Health and Human Services reserves the right to pursue legal action at its discretion.

Fees:

There will be no fee for the consideration of a Request for Data.

There will be a $50.00 fee for the preparation of a Data Use Agreement.

Instructions for payment will be provided when a Data Use Request is approved.

A waiver of this fee will be granted to graduate students on request if they do not have a grant or a faculty or institutional sponsor to pay the fee.